



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,528	03/23/2001	Roger D. Kamm	0492611-0375 (MIT-8802)	5331

7590 05/02/2003
C. Hunter Baker, M.D., Ph.D.
Choate, Hall & Stewart
53 State Street
Exchange Place
Boston, MA 02109

EXAMINER

YU, JUSTINE ROMANG

ART UNIT	PAPER NUMBER
----------	--------------

3764

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,528

Applicant(s)

KAMM ET AL. *Cr*

Examiner

Justine R Yu

Art Unit

3764

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30, 32 and 34-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30, 32, and 34-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 3764

DETAILED ACTION

1. This office action is responsive to the amendment filed on 2/12/03. As directed by the amendment, claims 1, 4-7, 15, 23, 32, 34, 35, 41, and 45 were amended, claims 31 and 33 were canceled, and no claim was added. Thus, claims 1-30, 32, and 34-54 are presently pending in this application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the compression apparatus in the independent claims, the inflatable bladder, bladder containing liquid, a series of cuffs containing at least one inflatable bladder, stretchable band, blood oxygen detector, pulse oximeter, EKG detector, blood pressure detector, heating or cooling means, means for accelerating the withdrawal of fluid, vacuum pump, negative pressure reservoir, mounting means, Velcro, buttons, snaps, elastic band, zippers, gas compressor, tank of pressurized gas, balloon, computer, and tension controlling means must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 3764

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Some examples of such errors are:

In claim 40, "liquid" lacks antecedent basis.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 32 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Lina (6,468,237).

Lina teaches a graded sequentially compressing device (column 13, lines 22-29, and column 16, table 1) for treating patients with low blood flow and wound (column 6, lines 55-64).

The deflation step reads on the step of applying negative pressure to the body part of the patient.

Art Unit: 3764

8. Claims 1, 9, 10, 13, 19-23, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Neeman et al (5,014,681).

Neeman teaches a method for treating low blood flow comprising steps of attaching a compression apparatus 3 to a body part of the patient and applying graded sequential compression (figure 10) to the body part with a maximum pressure less than 200 mmHg (column 7, lines 13-15).

9. Claims 1, 9, 10, 12, 13, 19, 20, 23, 25, 26, are rejected under 35 U.S.C. 102(b) as being clearly anticipated by McEwen et al (5,843,007).

McEwen teaches a device having the same structure as claimed including a plurality of cuffs (4, 6) (figure 2) for applying graded sequentially compression to the body (column 7, lines 26-28).

10. Claims 35-37, 39, 40, 44, 47, 49, and 51- 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Zheng et al (5,997,540).

Zheng teaches a device having a plurality of sequentially inflatable balloons 25 (column 8, lines 39-42), peak pressure 60 mm Hg (column 14, lines 30-31), and a computer 7. Zheng in column 5, lines 15-24 and column 14, lines 22-24 discloses a blood oxygen detector, pulse oximeter, blood pressure detector. Zheng further discloses a cooling means 21, and a mounting means within the cuff for mounting the cuff to the body (figure 4C).

Art Unit: 3764

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 2-8, 11, 12, 14-18, 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neeman et al.

Regarding claims 2 and 27-30, Neeman does not explicitly disclose that the patient having a wound or with different diseases. The feature of using the compression method to treat patients with such diseases is considered as an obvious design preference within the knowledge of one skilled art.

Regarding claims 3-8, 12, and 14-18, it would have been obvious to a skilled artisan that Neeman's device would be able to perform the recited function since Neeman's device has the same structure as claimed.

Regarding claim 11, the feature of choosing a maximum delivery pressure such as less than 150 mm Hg is considered as an obvious design choice since using less than 150 mm Hg is well known in the art.

Art Unit: 3764

13. Claims 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neeman et al in view of Dillon (5,514,079).

Neeman does not explicitly disclose the compression is timed with cardiac cycle of the patient. However, Dillon teaches a pulse monitor 13 having an EKG 14 and timer 16 (column 6, lines 9-19). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Neeman's device with a pulse monitor as taught by Dillon in order to enhance the treatment effect.

14. Claims 1-12, 14-22, 24-30, 35, 41-46, 48, 50, and 52-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cariapa et al (5,437,610).

Cariapa teaches a hydraulic system including sequentially compressible bladders (figures 1, 2) being attached to a body part of the patient. Cariapa lacks a detail description that the compression delivers a maximum pressure of less than 300, 250, 200, or 150 mm Hg. However, the feature of choosing the maximum compression pressure of less than such particular values are considered as obvious design choices, as is necessary and inherent upon various applications and providing compression to the patient within a safety range.

Regarding claim 21, the feature of attaching the compression device to the arm instead of the leg is considered as an obvious design choice since it appears that Cariapa's device would perform equally well by applying the device in the arm.

Regarding claim 25, figure 2 of Cariapa shows a series of cuffs each including an inflatable bladder.

Regarding claim 26, figure 1 of Cariapa shows the flexible band 24.

Art Unit: 3764

Regarding claims 41-43, notes the withdrawal pump 28 and reservoir 30.

Regarding claims 44-46 and 54, Cariapa teaches a Velcro 94 (mounting means or control means) but lacks buttons, snaps, elastic bands, or zippers. However, the feature of choosing different mounting means such as buttons, snaps, elastic bands, or zippers is considered as an obvious design choice since such mounting means are well known in the art.

15. Claims 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cariapa et al (5,437,610) in view of Dilton.

Cariapa lacks an EKG. However, Dilton teaches an EKG. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide Cariapa's device with an EKG as taught by Dilton, so as to provide a better control during the treatment.

Response to Arguments

16. Applicant's arguments see remarks, filed 2/12/03 have been fully considered but not persuasive.

Applicant on page 8 of the remarks argues that "liquid" can be found in claim 35. However, claim 35 merely has support for "fluid", not "liquid". Thus, the rejection stands.

The applicant on page 9 of the remarks argues that Neeman does not teach graded sequential compression, wherein the pressure applied at the distal region of the limb is greater than the pressure applied at a more proximal region. The argument is not well taken because according to the Webster's II New Riverside University Dictionary, the term "grade" means a stage or degree in a process; Neeman in column 2, lines 5-13 discloses the compressive wave

Art Unit: 3764

traveling in a desired direction with successive portions of the body part being subjected to compression; and figure 10 of Neeman clearly shows that the cells A-G and H-L being graded and sequentially inflated/deflated. Thus, Neeman reads on the claimed structure. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the pressure applied at the distal region of the limb is greater than the pressure applied at a more proximal region on page 9 of the remark) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The applicant on page 10 of the remarks argues that McEwen does not teach graded sequential compression. The examiner disagrees. McEwen in column 7, lines 26-29 clearly states that "instrument 2 may be connected to only one sleeve, or two sleeves of different design applied to the same limb for applying pressure waveforms sequentially in time." Thus, McEwen does teach the graded sequential compression.

The applicant on page 10, the third full paragraph of the remarks further argues that Zheng does not teach a device including a control means that provides graded sequential compression. The examiner disagrees. Zheng in column 8, lines 39-42 clearly states, "the balloons being sequentially inflated as the piston moves towards the second end of the cylinder." Zheng does teach control means that provides graded sequential compression.

The applicant on page 11, the last paragraph of the remarks argues that maximum pressure limitation is not an obvious design choice because Cariapa and the applicant have two different goals in mind: Cariapa is using the device for treating edema while the present

Art Unit: 3764

invention is directed to a method and apparatus for inducing angiogenesis or wound healing.

While it is true Cariapa's intension is for treating edema, however, it is well known in the art that using compressing device to treat different diseases, and the patent receiving treatment must not exceed a safety range. For example, McEwen teaches using 180 mmHg and 50 mmHg (both are less than 300) (column 13, lines 1-9) for treating lymph edema in the patient. In addition, Lina teaches using pressure range from 120-200 mm Hg (less than 300 mm Hg) for various patients including edema, wound healing, venous stasis, and poor circulation, etc., see teaching in column 4, lines 40-46 and column 6, lines 59-64 of Lina. Therefore, the feature of choosing a particular pressure within the safety range to treat the patient, i.e., less than 300 is a design consideration within the knowledge of skilled in the art and fails to patentably define over the prior art.

Response to Amendment

17. The Declaration under 37 CFR 1.132 filed 2/12/03 is sufficient to overcome the 35 USC 101 and 112 (1) rejection of claims 3-7, 12, and 14-18 based upon experimental results disclosed in the declaration.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after


Art Unit: 3764

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Justine R Yu whose telephone number is (703)308-2675. The examiner can normally be reached on 8:30am - 6:00Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (703)308-2698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.


Justine R Yu
Primary Examiner
Art Unit 3764

JY
April 25, 2003